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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,144	11/25/2003	Robert J. Hariri	ANTH-0004	6313

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EXAMINER	
MCGILLEM, LAURA L	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,144	HARIRI, ROBERT J.	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37 and 50* is/are pending in the application.

4a) Of the above claim(s) *11,14,25,30 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12,13,15-24,26-29,31,32,34-37 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

It is acknowledged that Applicant has amended claims 1, 6-10, 12-13, 18, 20, 22-23, 26, 28, 31, 34 and 50, in the response filed 11/7/05. Claims 11, 14, 25, 30, 33, 38-49 and 51-53 have been canceled.

Claims 1-10, 12-13, 15-24, 26-29, 31-32, 34-37 and 50 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is rejected as vague and indefinite because it recites "cells derived from umbilical cord blood" and it is not clear in what way the cells will be "derived from" cord blood.

This rejection is maintained for reasons of record in the previous Office action mailed 10/4/05 and for reasons outlined below.

Applicant has amended claim 34 to replace the word "derived" in line with the word "obtained", but the claim has been further amended in (c) to add the phrase "cells derived from umbilical cord blood" and therefor the claim remains unclear regarding what way the cells will be "derived from" umbilical cord blood.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12-13, 15-24, 26-29, 31-32, 34-37 and 50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cytotherapeutic unit comprised of CD34+ and CD8+ cells for treatment of patients in need of hematopoietic cells, does not reasonably provide enablement for all other potent cell types for treatment of all disease states or conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant claims a cytotherapeutic unit, a library of cytotherapeutic units and a kit comprising a plurality of potent cells including pluripotent cells with known identities and numbers obtained from a plurality of sources including fetal cord blood, fetal tissue, placenta or placenta perfusate selected to be suitable for therapy for an indicated disease state or condition. The instant claims are drawn to therapy for any type of disease state or condition, which encompasses an incredibly broad and diverse group.

This rejection is being maintained for reasons of record in the previous Office action, mailed 10/4/05 and for reasons outlined below.

Applicant submits that the application references well-known techniques for extracting cells from tissues, cord blood, placenta, etc. and references well-known

techniques for identifying assaying, counting, sorting, separating and storing said cells. Applicant submits that although some experimentation might be necessary to optimize the types and numbers of cells to administer to a patient with a condition, the experimentation would not be undue experimentation. Applicant submits that a physician typically determines efficacy of a medical treatment in a routine manner. Applicant further submits that the potential for "variations in therapeutic effect" and "side effects" are not uncommon for most medical treatments and that such side effects have relevance to the Food and Drug Administration rather than the Patent and Trademark Office. Applicant suggests that the use of the Wobus and Boheler paper to illustrate poor development of the stem cell field was taken out of context, and instead supports enablement of the instant invention.

Applicant's arguments filed 11/7/05 have been fully considered but they are not persuasive. Although Applicant has amended the instant claims to limit the cells in the cytotherapeutic unit to cells from a plurality of sources wherein one source of the plurality is fetal cord blood, fetal tissue, placenta or placenta perfusate, the claims are still drawn to a very large group of cells, including unspecified cells from unspecified types and amounts of fetal tissue.

The claims are also drawn to the use of said cells for a cytotherapeutic treatment of a very large group of ANY type of disease or condition. The instant specification discloses a non-limiting list of potential disease or conditions for which the cytotherapeutic unit might be useful which includes conditions as diverse as Alzheimer's disease and breast cancer (paragraph 0053). Therefore, the issue at hand is not

whether there are art-recognized methods of extracting any type of cell from said tissues, or characterizing and storing the cells in question. The issue is whether the instant specification has taught how to make or use a cytotherapeutic unit with any type of cells from fetal cord blood, fetal tissue, placenta or placenta perfusate as an effective therapy for ANY disease state such as Alzheimer's or Parkinson's disease, as well as various cancers such as melanoma or pancreatic cancer. The skilled artisan would recognize that any one of these disease states or conditions are complex in their manifestations, course of disease, patient population and response to treatment. Applicant submits that the specification directs the skilled artisan to adjust the cytotherapeutic unit as needed for treatment of acute myelogenous leukemia, sickle cell anemia and adrenal leukodysplasia, according to patient's weight and disease severity, where adjustment may include administration of a second transplant. Further, Applicant submits that physicians routinely determine efficacy of a treatment for an individual with a condition with attention to factors such as patient condition, weight and disease severity and would be able to determine such for customizing the claimed cytotherapeutic unit. However, considering the broad types and number of cells for potential use to treat almost any type of disease, a skilled artisan would have to conduct trial and error experimentation for each combination of plurality of cells in the cytotherapeutic unit for each type of disease, and possibly for each individual in need of treatment. This constitutes an excessive amount of trial and error experimentation.

In response to the Examiner's citation of Gerlach et al (of record) to support the unpredictability of a stem cell-based therapeutic based on multiple art-recognized

problems associated with stem cell treatment such as uncontrolled proliferation, Applicant submits that variations in therapeutic effect and side effects are not unusual for most medical treatments. However, it is unlikely that most patients with any disease state or condition would consider uncontrolled stem cell proliferation (i.e. cancer) to be a "part and parcel" side effect. This is not an issue relevant to the FDA, instead it is indicative of Applicant's failure to teach the skilled artisan how to make and use the claimed invention. Citation of Wobus and Boheler and Gerlach et al are meant to illustrate that stem cell therapeutics are at the present time unpredictable. Wobus and Boheler do teach that stem cell therapeutics have potential for success based on success in animal models, but also teach with multiple art-recognized problems such as immunogenicity, tumorigenicity, control of differentiation and ethical issues which must be addressed before widespread use (see page 662, right column, last paragraph, and page 667, right column, 1st full paragraph, for example). The cited references are used to demonstrate that the ability to make and effectively use the claimed unit for human therapeutics is unpredictable. Evaluation of unpredictability of the art is one of the factors that must be used to determine whether undue experimentation is required to make and use the claimed invention (Enablement) and is relevant to the allowance of patent claims by the Patent and Trademark Office.

Conclusion

No claims are allowed. Any previous rejections not addressed herein are withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura McGillem, PhD
1/5/2006

DAVID GUZO
PRIMARY EXAMINER